

COMMISSION DECISION

of 13 July 1987

relating to a proceeding under Article 85 of the EEC Treaty
(IV/31.741 — Sandoz)

(Only the Italian text is authentic)

(87/409/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation No 17 of 6 February 1962, first Regulation implementing Articles 85 and 86 of the Treaty ⁽¹⁾, as last amended by the Act of Accession of Spain and Portugal, and in particular Articles 3 (1) and 15 (2) thereof,

Having regard to the Commission Decision of 15 April 1986 to initiate proceedings in this case on its own initiative,

Having given the undertaking concerned, Sandoz Prodotti Farmaceutici SpA, the opportunity to make known its views on the objections raised by the Commission, pursuant to Article 19 (1) of Regulation No 17 and Commission Regulation No 99/63/EEC of 25 July 1963 on the hearings provided for in Article 19 (1) and (2) of Council Regulation No 17 ⁽²⁾,

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Whereas

I. THE FACTS

A. Subject of the Decision

- (1) This Decision concerns the commercial relationship between Sandoz Prodotti Farmaceutici SpA and its customers. It concerns, in particular, an export ban.

B. The undertaking

- (2) The undertaking to which this Decision is addressed is Sandoz Prodotti Farmaceutici SpA, the Italian subsidiary of the Swiss group Sandoz. The Sandoz

group, which has its head office in Basle, Switzerland, is a multinational company of major importance. Its subsidiaries operate in all continents in a total of 44 countries and as producers in 34 of them. In the Community, companies of the Sandoz Group are present in all the Member States except Luxembourg. The Group is active in a variety of sectors (1985 turnover: SwF 8 453 million; about ECU 4 870 million), the principal ones being pharmaceuticals (1985 turnover: SwF 3 912 million; about ECU 2 253 million), dyestuffs and chemical pigments (1985 turnover: SwF 2 107 million; about ECU 1 213 million), nutritional products (1985 turnover: SwF 1 121 million; about ECU 645 million), agricultural ('agro') products (1985 turnover: SwF 601 million; about ECU 346 million), and the production of seeds and biotechnological research.

- (3) The Italian subsidiary of the Sandoz group was founded in the 1920s under the name of Sandoz SpA. The undertaking operated under this name until 31 December 1983. From 1 January 1984, the pharmaceuticals side of the business was separated from the chemicals side and assigned to two separate companies: Sandoz Prodotti Farmaceutici SpA (hereinafter referred to as Sandoz PF) and Sandoz Prodotti Chimici SpA. In Italy (at its Milan plant) Sandoz PF produces all the proprietary medicinal products and over-the-counter products of the Sandoz range, except for those which, mainly for technical reasons, are still manufactured and exported from Switzerland. Sandoz PF is also the distributor in Italy of the pharmaceutical products which it produces or imports. In the last financial years the turnover of Sandoz SpA's pharmaceuticals division (up to 1983) and then of Sandoz PF (from 1984) was the following: 1981: Lit 70 600 million (about ECU 56 million); 1982: Lit 84 100 million (about ECU 63,5 million); 1983: Lit 99 900 million (about ECU 74 million); 1984: Lit 109 800 million (about ECU 79,5 million); 1985: Lit 97 614 million (about ECU 66 million).

⁽¹⁾ OJ No 13, 21. 2. 1962, p. 204/62.

⁽²⁾ OJ No 127, 20. 8. 1963, p. 2268/63.

C. The product

- (4) The products to which this Decision refers are the pharmaceutical products distributed by Sandoz PF and more particularly its proprietary medicinal products.
- (5) Except for a few differences sometimes to be found in the packaging or the wording and the names generally expressed in the local language, these products are the same as those distributed by other Sandoz subsidiaries in the Member States.

D. The market

- (6) As stated by the Commission in its Fourteenth Report on Competition Policy, the European pharmaceutical market is large in total but is divided along both national and regional lines. The reasons behind this division stem mainly from differences in Member States' laws for the regulation of prices and the admission of pharmaceutical products to markets. Parallel trade and pressure to make more use of generics have emerged as ways in which a greater degree of price competition might be introduced. For the time being, the current flow of parallel trade seems to represent no real threat for the industry.
- (7) The market in pharmaceutical products in Italy is controlled by the national legislation which governs the production of and trade in drugs. The more specifically relevant provisions are Articles 143 to 189 of the consolidated health laws ('Testo Unico delle Leggi Sanitarie') (Royal Decree No 1265 of 27 July 1934), Articles 2, 6, and 28 to 31 of the Health Reform Law ('Legge della Riforma Sanitaria') (Law No 833 of 23 December 1978 establishing the National Health Service), the provisions of the Regulation implementing the said consolidated laws (Royal Decree No 478 of 3 March 1927), and various laws, regulations and administrative circulars (in particular, for prices, Law No 395 of 11 July 1977).
- (8) In accordance with the abovementioned legislation, the main characteristics of the Italian pharmaceutical market can be summarized as follows:
- administrative authorization is required for production and marketing,
 - in order to obtain this authorization, the product must be registered: the Ministry for Health must be supplied with full documentation specifying, *inter alia* the drug's technical characteristics,

costs, the establishment where it is produced, its packaging, its label, and the leaflet to be enclosed in the package. On the basis of this information, the Ministry decides whether or not to grant the authorization and, if authorization is granted, it issues an appropriate Registration Decree,

- this Decree *inter alia* fixes the price at which the drugs are to be sold to the public; this may not be varied in any way, except for the periodic review carried out by the same competent administrative authority. For 'proprietary medicinal products' the authorities use a special procedure to establish the price which is fixed by the Decree; for 'over-the-counter products', the price is decided by the producer and subsequently controlled on the market by the authorities,
 - drugs are resold to the public solely by pharmacies, who hold the concession for a specific 'territory' for which they are responsible,
 - under the present system, the final consumer generally does not pay for the drug (it is largely paid for by the State, through the direct health insurance scheme) nor does he choose it (it is chosen by the attending doctor who prescribes it for the patient),
 - proprietary medicinal products may not be advertised and only scientific information for doctors is permitted.
- (9) The Italian pharmaceutical industry — which includes foreign producers established in Italy — has on several occasions raised and indicated the problems which they say the present system of administered prices causes them, whereby prices are set at levels which are among the lowest in the EEC. Some 300 Italian and foreign pharmaceutical companies, mainly funded by private capital, operate on the Italian market. Within the Italian market, Sandoz PF, with a turnover in 1985 of Lit 97. 614 million (about ECU 66 million), is one of the 10 largest undertakings.

E. The subject of the proceedings

- (i) *The commercialization of Sandoz products*
- (10) The customers of Sandoz PF, as distributor of the Sandoz range of pharmaceutical products in Italy, are wholesalers (some 300), pharmacies (several

thousand) and hospitals. The commercial organization is directed from the Milan head office and comprises various depots in the rest of the country.

- (11) When a new customer wants to buy Sandoz PF's products he has to send a letter explaining, in particular, his financial position and guarantees, as well as his equipment and distribution structure. Sandoz PF examines this documentation and makes a visit to the customer's premises in order to verify the situation on-the-spot. Afterwards Sandoz-PF requests the opinion of the Italian Association of Pharmaceutical Industries (Farmindustria). Thereafter the customer receives a 'notation' on the basis of which the general sales conditions are established by Sandoz PF. These conditions refer in particular to the payment procedure (in advance/on receipt of the goods/10; 15 or 30 days after receipt) and to the regularity of the orders to be made by each customer.
- (12) Once the above described procedure is concluded, if the evaluation is favourable, Sandoz PF starts delivering to the customer. Every customer knows his position, which is on the basis of the 'notation' received: therefore he is aware of the sales conditions which rule his relations with the seller. It is normal for a customer to continue to deal regularly with Sandoz PF over a period of years on the same terms. If nothing happens to modify the viability of a certain customer — an increase or decrease — the same conditions continue to apply. This type of system is the usual one in the pharmaceutical sector in Italy in the sense that such systems are applied by all pharmaceutical producers following the criteria established by Farmindustria.
- (13) Customers place their orders mainly by telephone, and almost all contacts between Sandoz PF and customers take place by telephone; contacts relating to general or particular matters would not be made in writing, except in rare, isolated cases. When the Sandoz PF sales office receives an order for products, an employee feeds it into the computer's memory, unless he notices something unusual; in that case he asks the customer for an explanation and immediately informs the sales manager. Every evening, the manager in any event checks the data memorized during the day and, if he considers it appropriate, can gain access to the computer to make changes.
- (14) In general, the main operations are checks to be carried out on new customers or customers whose solvency is in doubt; sometimes, when quantities ordered are greater than the 'normal' average of a

certain client or when they do not correspond to what Sandoz PF considers to be the 'normal' consumption for the territory covered by a given customer, they may be reduced. The Commission's enquiry shows that Sandoz PF quite often reduces its customers' orders. The reasons for these reductions in customers' orders are varied and, as will be examined in the next section, may be connected with particular economic situations which determine an increase in demand.

- (15) Once the order has been memorized by the computer it has to be executed, and the sales office sets in motion the procedure for delivering the goods: it prepares the accompanying delivery note, orders the warehouse to prepare the packaging, and invoices and sends the goods to the consignee who pays the bill. Save for a few cases (e.g. the beginning of the commercial relationship between Sandoz PF and its clients, or in cases of sales to customers of doubtful viability) where payment is requested in advance, the invoice is usually sent to the customer after delivery of the goods. For clients of greater viability, payment is generally made after receiving the invoice — 10, 15 or 30 days later — according to the sales conditions applied to the particular client.

(ii) Aspects of distribution more directly connected with 'parallel trading'

- (16) According to Sandoz PF, 'parallel trading' is a marginal phenomenon and quite rare in terms of the company's overall distributive activity. However, since this is a question of major importance for the Italian pharmaceutical industry, Sandoz PF has dealt with the subject several times, both as regards relationship within the industry and as regards Sandoz PF itself. In general terms, Sandoz PF makes the point that parallel trading occurs in Italy by means of export flows to other foreign markets, where the demand is such as to enable an independent operator to make a profit on the difference between the resale price and the price he paid on the Italian market when acquiring the goods. According to Sandoz PF, therefore, the cause and the main reason for parallel trading is the low level of prices set by the public authorities in Italy.
- (17) As far as Sandoz PF is aware, various wholesalers and pharmacies are active as parallel exporters, either regularly or intermittently, and their destinations include other Member States. However these are merely suspicions, since the company has no means of ascertaining the subsequent destinations

of the products it distributes. With regard to the range of products distributed, Sandoz PF states that it has noted somewhat greater sensitivity to parallel exporting for the following drugs; Methergin, Visken, Calcium Forte and Sandomigran.

invoices used by Sandoz PF bore the words 'export prohibited'. According to the company, this kind of invoice had been introduced before the creation of the Community. The Commission considers, and Sandoz PF agrees, that the words 'export prohibited' always figured on the invoices after the entry into force of the Treaty of Rome.

- (18) As regards a possible connection between any reductions in customers' orders and parallel trading, Sandoz PF stresses that there could be many causes for such reductions. Of these, the most common are for example those which occurred at particular periods of the year when customers tended to order greater quantities to take advantage of the possibility of late payment (as in the case of 'holiday orders', which were made in June or July and not paid until a month later because of the summer holidays); another structural cause might be a warehouse shortage because stocks of a given product were exhausted (this happens, for example, with beginning-or end-of-year orders). Sandoz also stresses that a warehouse shortage could be connected with special local situations, often temporary in nature, for example, war pushing up the demand for drugs. Therefore, from a general point of view, Sandoz PF stresses that the said reductions in orders would be a marginal phenomenon connected mainly with the overriding need to plan its production, warehouse policy and distribution in accordance with its fundamental role of Italian subsidiary of the Sandoz group.

- (19) In this connection, according to the statements made by Sandoz PF, reductions which were somehow connected with parallel trading would be extremely rare and would relate to a few marginal cases (such as those referred to during the investigation visit of 13 February 1985). It results from the documents examined by the Commission that Sandoz PF fairly systematically reduced customers' orders. However, the company has produced evidence in order to show that there was no relationship of cause and effect between the cutting of orders and any intention of discouraging parallel exports.

(iii) *The invoices used*

- (20) The invoices used by Sandoz PF are printed on the front only; no standard sales conditions are printed on the back. However, some standard sales conditions are printed on the front of the invoice. These conditions include the competent jurisdiction (Milan), apportionment of transport risks and the time limit for introducing a complaint following the delivery of the goods. Until the most recent change made by Sandoz PF after receiving the request for information, pursuant to Article 11 of Regulation No 17, which was sent on 26 November 1984, the

- (21) These words were situated in the top right-hand corner of the invoice form in use until 31 December 1983. Afterwards, when the Italian subsidiary of the Sandoz Group was restructured, changes were made to the invoice involving the corporate name and the general layout: in particular, the words 'export prohibited' were moved to the bottom of the invoice, and centred. The latter form came into use on 1 January 1984 and was in regular use in relationships with customers when the Commission sent the abovementioned letter. In its reply of 22 January 1985 to the abovementioned Article 11 letter, Sandoz PF stated that it had arranged for the words in question to be provisionally deleted and be permanently removed, having ordered new invoice forms which were to replace the earlier ones.

- (22) Sandoz PF stresses that the presence of the said words was due to a 'mere oversight' and to 'an incomplete implementation of a company instruction' in which 'the company's management directed that the words 'export prohibited' should no longer appear anywhere or be used in any way'. It was explained that these instructions were issued by the Sandoz parent company in Basle, which ordered furthermore the removal of the words in question from all drug packaging and from invoices. However, Sandoz PF was unable to provide a copy of the instructions.

- (23) In the course of the Commission's enquiry, Sandoz PF stated that the existence of company instructions ordering the removal of every mention of 'export prohibited' was confirmed by the fact that until the early 1970s (the company is not able to specify the exact date) the packaging of Sandoz pharmaceutical products also carried these words which were later removed, as is the case today.

(iv) *Other subsidiaries of the Sandoz group*

- (24) The visits made to the subsidiaries of the Sandoz Group in Belgium, the United Kingdom and France showed *inter alia* that those companies never used invoices bearing the words 'export prohibited' or

equivalent phrases. None of those Sandoz subsidiaries, or the Sandoz parent company, were able to produce, or remember, any written group instructions about the removal of these words from invoices. For those subsidiaries, the Sandoz pharmaceutical products generally considered to be in greater demand by the parallel market are Methergin, Visken and Calcium Forte.

II. LEGAL ASSESSMENT

A. Article 85 (1)

- (25) Although no written general contract exists between Sandoz PF and its customers, it must be considered that the type of agreement referred to in Article 85 is represented by the continuous commercial relationship set up and concretised by the whole of the above-described commercial procedures normally provided for by Sandoz PF in its relations with its customers and at least implicitly accepted by them.
- (26) Consequently, the invoice cannot be seen as the expression of a merely unilateral act but forms part of such an agreement of which it constitutes the documentary evidence. The fact that the invoices have been constantly and systematically used leads to the conclusion that Sandoz PF's clients implicitly agreed with it and accepted it.
- (27) Hence the words 'export prohibited', which appear on the invoices used by Sandoz PF, represent, with regard to Article 85, a contractual clause forming an integral part of the agreement on which Sandoz PF and its customers base their transactions. This is confirmed by the presence, on the front of the invoices, of certain other commercial clauses relevant to clients. The fact that Sandoz PF claims that these clauses are void or simply respecting the Italian Civil Code does not affect their nature as sales conditions.
- (28) In the light of the above, the Commission considers that the adoption and acceptance of sales invoices bearing the clause 'export prohibited', in so far as it has to be considered an element of the above-described agreement between the parties, is an infringement of Article 85 (1). In particular, such a provision undoubtedly has as its object the

prevention, restriction or distortion of competition within the common market, and may affect trade between Member States. Furthermore, the continual use of such invoices is likely to have the effect of discouraging those customers who are less aware of Community law from exporting Sandoz PF's products.

- (29) By prohibiting exports, the clause in the agreement between Sandoz PF and its customers constitutes by its very nature a restriction of the competitive opportunities available to economic agents as a result of the establishment of the European common market. Through such agreements companies can compartmentalize the national markets to a considerable extent, thereby affecting trade between the Member States and contravening the basic aims of the Community.
- (30) Furthermore, in the framework of a commercial relationship such as described above, the seller's practice of reducing quantities ordered by its clients to what it considers to be their 'normal' demand may be an element of an agreement between the parties, in particular when it constitutes a well known and systematically applied commercial policy on a market characterized by active parallel trade. In such cases, where no different explanation exists, the reductions may be taken as evidence of an effort to prevent parallel trading. However, in the present case, no sufficient elements have been established to conclude that the reductions practised by Sandoz PF are systematically made with that objective.

B. Article 85 (3)

- (31) The agreement in question between Sandoz PF and its customers was not notified to the Commission; therefore, it cannot be exempted. In any event, such an agreement, even if it had been notified, would be unlikely to obtain an exemption because it is clearly opposed to Community competition rules since it imposes a serious restriction which is not indispensable to a proper sales system and is likely to be detrimental to consumers.

C. Article 3 of Regulation No 17

- (32) The Commission accepts that the invoices bearing the words 'export prohibited' have since 1985 been

removed; likewise the Commission accepts that, since at least the beginning of the 1970s, the packaging of Sandoz PF drugs has not carried any prohibition of export. However, it is necessary to require Sandoz PF to refrain from seeking to reimpose such restriction by any other means.

D. Article 15 (2) of Regulation 17

(i) *Liability of Sandoz PF*

(33) This Decision is addressed only to Sandoz PF because it alone must be held responsible for the infringement of Article 85 (1). As argued above, the export prohibition printed on the invoice must to all intents and purposes be considered to be a clause of the agreement between Sandoz PF and its customers and not a unilateral act. However, it must also be noted that the said invoice and the said clause were prepared and adopted by Sandoz PF itself. The export ban was set up in the essential interests of Sandoz PF, which was ultimately responsible for its creation and application and for any measures taken to ensure its practical effects on the market. Therefore, Sandoz PF's clients cannot be considered responsible for the infringement.

(34) As is clear from the foregoing, the invoices in question were adopted by Sandoz PF which could not have been unaware that the export ban had as its object the restriction of competition on trade between Member States. Consequently, it is of little relevance to establish whether or not Sandoz PF knew that it was infringing the prohibition contained in Article 85. Therefore it can only be concluded that the acts prohibited by that Article were undertaken intentionally. However, even if Sandoz PF's thesis of a 'mere oversight' were to be accepted, this would not exclude its liability and would represent a grave form of negligence.

(35) As explained above, Sandoz PF has stated that it was as a result of a 'mere oversight' that the invoice in question bore the words 'export prohibited', and that anyway the company had taken no steps to enforce the prohibition. However, on this point, it must be recalled that the words 'export prohibited' were found on the top right-hand corner of the invoice in use until 31 December 1983, and were then moved to the bottom centre of the new invoice introduced from 1 January 1984, after the corporate name was changed. It is precisely because the words

in question were moved that an actual recurrence of the 'mere oversight' is scarcely plausible. Indeed, it is rather difficult to imagine that the new invoice form, on which several significant changes were made compared to the earlier one, was examined and checked so superficially by the competent departments of Sandoz PF as to let slip an 'oversight' of such clear and evident commercial and legal importance, particularly to an important subsidiary of a multinational group.

(36) As regards the Sandoz PF comment on the removal of the words 'export prohibited' which, at least up to 1970, still appeared on its drug packaging, it must first be stressed that, rather than strengthening the validity of the 'oversight' argument, the fact that the packaging was brought into line with the EEC rules is evidence of another occasion on which Sandoz PF should have brought the invoice into line with such rules. It must also be pointed out that even before 1970 it was clear that Community law did not permit undertakings to prohibit exports between the Member States. Therefore, the fact that Sandoz PF also retained this prohibition until the said date on the individual drugs packagings it distributed, as well as its invoices, is an aggravating and not an extenuating circumstance.

(ii) *Duration of the infringement*

(37) For the reasons mentioned above, the Commission considers that the invoices adopted by Sandoz PF and accepted by its customers always bore the words 'export prohibited' from the entry into force of the Treaty of Rome until the end of 1984.

(iii) *Fines*

(38) For infringement of Article 85, the Commission may impose under Article 15 (2) of Regulation No 17 a fine of up to one million ECU or up to 10 % of the turnover of each undertaking in the preceding business year, if the latter amount is the greater. In determining the fine, regard is to be had to both the gravity and the duration of the infringement.

(39) The Commission, in this case, in deciding the level of the fine, has taken account of the clarity of Community law relating to the obstruction of the achievement of a fundamental objective of the Treaty, the integration of a single common market. It has also considered the very serious nature of at least a gravely negligent infringement of the EEC competition rules by Sandoz PF, which explicitly

prohibited exports in an agreement for a particularly long period and only brought the prohibition to an end in 1985 following the Commission's intervention. Account has also been taken of the economic importance and turnover of the undertaking and the fact that it is part of a large and experienced group of companies. On the other hand, in defining the amount of the fine, the Commission has also taken account of the impact of national government measures on trade and competition within the Community.

HAS ADOPTED THIS DECISION:

Article 1

Sandoz Prodotti Farmaceutici SpA (hereinafter Sandoz PF) has infringed Article 85 (1) of the EEC Treaty by providing for an export ban in the commercial relationships with its clients.

Article 2

Sandoz PF, which ended the infringement in 1985 after Commission intervention, is hereby required to refrain, in relation to the sales of its products, from any agreement and/or concerted practice which may have the same or similar object or effect.

Article 3

A fine of 800 000 ECU is hereby imposed on Sandoz PF. This amount shall be paid into the Commission's account No 9-130-707 — Commissione delle Comunità Europee, Bruxelles — ECU, at: Istituto Bancario San Paolo di Torino, 156 Piazza San Carlo, I - 10121 Torino, within three months from the date of notification of this Decision. On expiry of that period interest shall automatically be payable at the rate charged by the European Monetary Cooperation Fund on its ECU operations on the first working day of the month in which this Decision was adopted, plus 3,5 percentage points, i.e. 10 %. Should payment be made in the national currency of the addressee, the exchange rate applicable shall be that prevailing on the day preceding payment.

Article 4

This Decision is addressed to:

Sandoz Prodotti Farmaceutici SpA,
Via Arconati, 1,
I-20135 Milano.

This Decision is enforceable pursuant to Article 192 of the EEC Treaty.

Done at Brussels, 13 July 1987.

For the Commission

Peter SUTHERLAND

Member of the Commission